Aetna Better Health®/Aetna Better Health® KIDS
Pharmacy and Therapeutics Committee (P&T)
Meeting Minutes

Date: **Time:** **Presiding:**	**2/6/2018** **5:30 PM** **Natalie Nkurunziza, Pharm.D, Pharmacy Director**	**Telephonic Attendance:** B. Lewin, MD, CMO; Richard Buzard, MD; Maislyn Christie, MD; A. D'Angelo, Director of Medical Management; G. Masciangelo, Clinical Liaison; Oluwatoyin Fadeyibi, Pharm.D, MPH; Robert Schreiber, RPh, Burns Pharmacy; Brad Tabaac, RPh, Friendly Pharmacy; Vicki Martin, MD, CCBH; Eileen Carroll, RN, Scribe* **Absent:** Barbara Wingate, MD; Romani George, MD, CCBH

* Nonvoting member(s)

TOPIC FOR DISCUSSION	SPEAKER	DISCUSSION	ACTION	DATE DUE
I. Call to Order	N. Nkurunziza, Pharm.D	The meeting was called to order at 5:39pm. Roll call was completed and quorum was established.	N/A	N/A
II. Announcements	N. Nkurunziza, Pharm.D	There were no announcements made at this time.	N/A	N/A
III. Review and Approval of Minutes	N. Nkurunziza, Pharm.D	Meeting minutes from the 11/1/2017 P&T meeting were reviewed and approved as written with a motion from B. Tabaac and a second from R. Buzard, MD. The motion carried without opposition.	The meeting minutes were approved.	Complete
IV. New Business				
A. 2018 P&T Charter	N. Nkurunziza, Pharm.D	2018 P&T Charter N. Nkurunziza, Pharm.D explained that charters are reviewed, revised and brought to committee for approval on an annual basis. There were no substantive changes made this year, in comparison to the 2017 version. Acronyms were added and/or spelled out throughout the body of the document, membership titles and documentation requirements were updated to align with the other quality committee charters. There were no questions, concerns, or suggestions for revision posed by the committee. B. Tabaac motioned to approve the 2018 P&T Charter as presented with a second from R. Schreiber. The motion carried without opposition.	The 2018 P&T Charter was approved.	Complete

<table>
<tr><th>TOPIC FOR DISCUSSION</th><th>SPEAKER</th><th>DISCUSSION</th><th>ACTION</th><th>DATE DUE</th></tr>
<tr><td>B. Formulary Change – Generics</td><td>N. Nkurunziza, Pharm.D</td><td>
<u>Formulary Changes - Generics</u>
N. Nkurunziza presented information related to Formulary Changes – Generics, as listed below. She noted that due to shortages of the generic for Tamiflu, the plan is currently allowing both brand and generic at the point of fill.

The following generics were added to the Aetna Medicaid formularies where permitted by state regulations, as they provided a value add to our members with no negative impact.

<table>
<tr><th>Generic Name</th><th>Branded product name</th></tr>
<tr><td>Atazanavir 150mg, 200mg, 300 mg Cap</td><td>Reyataz</td></tr>
<tr><td>Efavirenz 50 mg, 200 mg Cap</td><td>Sustiva</td></tr>
<tr><td>Estradiol 0.1% Cream</td><td>Estrace</td></tr>
<tr><td>Oseltamivir 6 mg/mL Susp</td><td>Tamiflu</td></tr>
<tr><td>Tenofovir 300 mg Tab</td><td>Viread</td></tr>
</table>

The following generics were NOT added to the Aetna Medicaid formularies, as they did not provided added value to our members.

<table>
<tr><th>Generic Name</th><th>Branded product name</th></tr>
<tr><td>Dactinomycin 0.5mg Inj</td><td>Cosmegen</td></tr>
<tr><td>Sildenafil 25 mg, 50 mg, 100 mg Tab</td><td>Viagra</td></tr>
<tr><td>Tigecycline 50 mg IV</td><td>Tygacil</td></tr>
<tr><td>Timolol Male 0.5% Soln</td><td>Istalol</td></tr>
<tr><td>Triamcinolone Acetate 40 mg Inj</td><td>Kenalog-40</td></tr>
</table>

There were no questions, comments or discussion surrounding the presented information.
</td><td>Informational – no action required.</td><td>N/A</td></tr>
</table>

TOPIC FOR DISCUSSION	SPEAKER	DISCUSSION	ACTION	DATE DUE
C. Drug Class Reviews	N. Nkurunziza, Pharm.D	Drug Class Reviews N. Nkurunziza, Pharm.D stated that Drug Class reviews look at all agents either within a therapeutic class or classes to assure that the formularies are optimized across the Medicaid line of business for each therapeutic treatment area. The list of drug classes that underwent review in Q1 2018 is as follows: **Drug classes that underwent review *without* formulary change recommendations:** Systemic Corticosteroids; Antidementia; Direct Renin Inhibitors Progestins; Anthelmintics; Intravaginal Progesterone Products Parkinson's Disease; Atypical Antipsychotics-Oral; PCSK9's DM (Biguanides); CNS Stimulants; Movement disorder (monoamine depletors) DM (Meglitinides); Cytokines and CAM antagonists; Non-stimulant ADHD medications **Drug classes that underwent review *with* formulary change recommendations:** Estrogens; Gout; Antidepressants Antifungals; DM (Sulfonylureas); Statins Androgens; DM (TZD's) In addition to the above listed drug classes *with* formulary change recommendations, recommendations for Calcitriol (Scorable Action Item [SAI]), Lidocaine Ointment (SAI) and Over the Counter (OTC) Formulary may be found on slides six (6) through twelve (12) of the attached Appendix. These are based on clinical efficacy, safety and national treatment guideline recommendations. **Discussion regarding Calcitriol:** R. Schreiber asked if there are any pediatric indications for calcitriol, in relation to the recommendation to remove the oral solution from the formulary.	The Drug Class Reviews and formulary re-commendations were approved as presented.	Complete

TOPIC FOR DISCUSSION	SPEAKER	DISCUSSION	ACTION	DATE DUE
C. Drug Class Reviews – Cont'd	N. Nkurunziza, Pharm.D	N. Nkurunziza, affirmed that this medication can be used in children as young as one year of age. R. Schreiber asked if this will create a dosing problem, and alluded to the member being required to puncture a capsule. N. Nkurunziza replied that making the oral solution non-formulary would require a benefit exception for pediatric members and would likely be approved. R. Schreiber verbalized understanding. **Discussion regarding Lidocaine Ointment:** R. Schreiber stated that certain insurers will pay for specific NDCs (National Drug Codes) for medications such as lidocaine ointments and generic Tamiflu for cost effectiveness, and asked if CVS could put similar edits into the system. N. Nkurunziza replied that plan does not currently have any type of edit to limit to certain NDCs, but that she will look into this matter further and bring the information back to the next meeting for discussion. **Discussion regarding OTC Formulary:** B. Lewin, MD asked if smoking cessation products are currently on the OTC formulary, and if not, he suggested that they be added. N. Nkurunziza agreed. B. Lewin, MD added that the OTC formulary is a work in progress and will be brought to committee on a quarterly basis to review additions and subtractions. B. Tabaac motioned to approve the Drug Class Reviews as presented, with a second from R. Schreiber. The motion carried without opposition.		

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D. Coverage Guidelines/Criteria Reviews	N. Nkurunziza, Pharm.D	Coverage Guideline/Criteria Reviews N. Nkurunziza stated that annual review of guidelines considers national treatment recommendations/guidelines as applicable for the topic at hand, factoring in formulary composition of like or related drug/drug classes. Guidelines were also reviewed with respect to impact to operational efficiencies relative to utilization control benefits provided. Summaries of the changes for the below list of drugs were provided to the committee for review, and detailed information may be found on slides fourteen (14) through twenty-two (22) of the attached Appendix. • Anthelmintics • Nonpreferred Antidepressants • Atypical Antipsychotics • Buprenorphine • Central Nervous System (CNS) Stimulants • Corlanor • Cytokines and CAM (Cell Adhesion Molecule) Antagonists • Diclegis • Direct Renin Inhibitors • Egrifta • Entresto • Hyperlipidemia Medications • Intravaginal Progesterone Products • Juxtapid/Kynamro • Lysteda/Tranexamic Acid Tablets • Makena • Multaq • Non-stimulant ADHD (Attention Deficit Hyperactivity Disorder)	The Q1 2018 Coverage Guidelines/ Criteria Reviews were approved as presented.	Complete

TOPIC FOR DISCUSSION	SPEAKER	DISCUSSION	ACTION	DATE DUE
D. Coverage Guideline/Criteria Reviews – Cont'd	N. Nkurunziza, Pharm.D	Medications • Otezla • PCSK9 Inhibitors • Xifaxan New Guideline reviews (which include criteria details) were presented to the committee for the drugs/drug classes listed below. Detailed information may be found on slides twenty-three (23) through twenty-nine (29) of the attached Appendix. • Emflaza • Estrace/Premarin Cream • Griseofulvin • Lidocaine 5% Ointment • Monoamine Depletors (Ingrezza, Austedo, Tetrabenazine) R. Schreiber motioned to approve the 1Q Coverage Guideline/Criteria Reviews as presented, with a second from V. Martin, MD. The motion carried without opposition.		
E. New Drug Coverage Provisions/ Abbreviated Drug Reviews	N. Nkurunziza, Pharm.D	<u>New Drug Coverage Provisions/Abbreviated New Drug Reviews</u> New Drug Coverage Provisions/Abbreviated New Drug Reviews, which include detail and explanation for class, indication, efficacy, formulary alternative(s) and pertinent comments were presented to the committee for the drugs/drug classes listed below. Detailed information may be found on slides thirty (30) through thirty-three (33) of the attached Appendix. • Benznidazole • Calquence • Fasenra	The New Drug Coverage Provisions/ Abbreviated Drug Reviews were approved as presented.	Complete

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E. New Drug Coverage Provisions/ Abbreviated Drug Reviews	N. Nkurunziza, Pharm.D	• Mepsevii • Parsabiv • Solosec. R. Schreiber motioned to approve the New Drug Coverage Provisions/ Abbreviated Drug Review**s** as presented with a second from B. Tabaac. The motion carried without opposition.		
V. Open Forum	All	B. Lewin, MD thanked attendees for their time, participation and input.	N/A	N/A
VI. Adjournment	All	The meeting adjourned at 6:40pm.	N/A	N/A
VII. Next Meeting		The next P&T Committee meeting is scheduled for May 1, 2018.	N/A	N/A

APPROVED: May 1, 2018 P&T Meeting

N. Nkurunziza, Pharm.D, Director of Pharmacy, Chair P&T

Eileen Carroll, RN, BSN
Quality Management Nurse Consultant, Scribe

Appendix

Quality health plans & benefits
Healthier living
Financial well-being
Intelligent solutions

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Pharmacy & Therapeutics Meeting

February 6, 2018

Agenda

AGENDA	T ME	PRESENTER
Call to order	1 min	N. Nkurunziza
Review of Minutes • **4Q 2017 Meeting**	5 min	N. Nkurunziza
Old Business - none		
New Business		
1. 2018 P&T Committee Charter	5 min	N. Nkurunziza
2. Annual Formulary Approval	5 min	
3. Formulary Changes	20 min	
4. Drug Class Reviews	20 min	
5. Coverage Guideline/Criteria Reviews	40 min	
6. New Drug Reviews	25 min	
Adjournment		N. Nkurunziza
Next Meeting:		

Formulary Change – Generics

Report to P&T of Generics Added in the Previous Quarter:

The following generics were added to the Aetna Medicaid formularies where permitted by state regulations, as they provided a value add to our members with no negative impact.

Generic Name	Branded product name
Atazanavir 150mg, 200mg, 300 mg Cap	Reyataz
Efavirenz 50 mg, 200 mg Cap	Sustiva
Estradiol 0.1% Cream	Estrace
Oseltamivir 6 mg/mL Susp	Tamiflu
Tenofovir 300 mg Tab	Viread

Formulary Change – Generics

Report to P&T of Generics that were NOT Added in the Previous Quarter:

The following generics were NOT added to the Aetna Medicaid formularies, as they did not provided added value to our members.

Generic Name	Branded product name
Dactinomycin 0.5mg Inj	Cosmegen
Sildenafil 25 mg, 50 mg, 100 mg Tab	Viagra
Tigecycline 50 mg IV	Tygacil
Timolol Male 0.5% Soln	Istalol
Triamcinolone Acetate 40 mg Inj	Kenalog-40

Drug Class Reviews - Summary

Drug Class reviews look at all agents either within a therapeutic class or classes to assure that the formularies are optimize for each therapeutic treatment area.

Drug classes that underwent review *without* formulary change recommendations:		
Systemic Corticosteroids	Antidementia	Direct Renin Inhibitors
Progestins	Anthelmintics	Intravaginal Progesterone Products
Parkinson's Disease	Atypical Antipsychotics-Oral	PCSK9's
DM (Biguanides)	CNS Stimulants	Movement disorder (monoamine depletors)
DM (Meglitinides)	Cytokines and CAM antagonists	Non-stimulant ADHD medications
Drug classes that underwent review *with* formulary change recommendations:		
Estrogens	Gout	Antidepressants
Antifungals	DM (Sulfonylureas)	Statins
Androgens	DM (TZD's)	

Drug Class Review – Estrogens (SAI)

The following class of agents were reviewed and the formulary recommendations were based on clinical efficacy, safety and national treatment guideline recommendations. Formulary optimization across the Medicaid LOB can be achieved for all plans.

Background:

- Currently all estrogens are on formulary except for the topical spray and gel, injectable, and Angeliq (Drospirenone-estradiol).
- Patches are associated with a lower risk of VTE, stroke, and hypertriglyceridemia than oral estrogens but have similar efficacy to oral estrogen (when given at similar doses).
- Vaginal estrogens are preferred for vulvar atrophy from menopause w/o vasomotor symptoms. In addition, The North American Society for Pediatric and Adolescent Gynecology (NASPAG) recommends short-term use of vaginal estrogen cream for the treatment of labial adhesions in symptomatic patients.
- Cost differences exist between products without notable clinical differences (within the same subclass):
  - Premarin versus oral estradiol ($150 vs $5 per Rx)
  - Prempro/Premphase versus estradiol-norethindrone or ethinyl estradiol-norethindrone ($175 vs $90 per Rx)
  - Climara Pro versus Combipatch ($185 vs $160 per Rx)
  - Premarin/Estrace cream versus vaginal estradiol tablets ($315 vs $175 per Rx)
  - Femring is the only vaginal estrogen that is FDA-approved for both vulvar atrophy AND vasomotor symptoms, but it is more expensive than oral estradiol or patches ($425 per Rx).

Drug Class Review – Estrogens (SAI)

The following class of agents were reviewed and the formulary recommendations were based on clinical efficacy, safety and national treatment guideline recommendations. Formulary optimization across the Medicaid LOB can be achieved for all plans.

Recommendations:

- Remove Premarin (GF=Y)
- Remove Prempro and Premphase (GF=Y)
- Remove Climara Pro Patch (GF=Y)
- Remove Femring (GF=Y)
- Add PA to Premarin cream and generic Estrace cream (GF=Y)
  - Smart edit to allow auto-PA for treatment of labial adhesions
  - PA guideline presented later
  - NOTE: generic version of Estrace cream became available after SAI was developed. Will review class at next P&T to determine if Premarin cream should be removed from formulary to drive utilization to the generic Estrace cream.
- Add QLL on Estring of 1 per 84 days

Drug Class Review – Antifungals (SAI)

The following class of agents were reviewed and the formulary recommendations were based on clinical efficacy, safety and national treatment guideline recommendations. Formulary optimization across the Medicaid LOB can be achieved for all plans.

Background:

- All generic oral antifungals are on formulary except for voriconazole
- The formulary includes both azole and non-azole antifungals and provides coverage of all first-line agents for the majority of infections
- Fluconazole and itraconazole are the preferred azole antifungals when an azole is indicated except for invasive aspergillosis where voriconazole is considered first-line
- Griseofulvin is the gold standard for treating children/adolescents with tinea capitus, but other formulary antifungals are appropriate as first-line for other dematophyte infections. Fluconazole is also available as a suspension and can be used in children.
- Griseofulvin cost per Rx ($75-$210) is more than other products: e.g., terbinafine ($6) or fluconazole ($6-$47)

Recommendations:

- Keep the following products on formulary: nystatin, terbinafine, ketoconazole, fluconazole, itraconazole
- Keep the following products as NF: Cresemba, Noxafil, voriconazole
- Add ST to griseofulvin through fluconazole, itraconazole, ketoconazole OR terbinafine. Smart edit to auto-PA for tinea capitus indication (PA GL presented later)

Drug Class Review - Formulary Changes

The following classes of agents were reviewed and contain minor formulary change recommendations. These recommendations were based on clinical efficacy, safety and national treatment guideline recommendations.

Drug Class	Drug	Description
Androgens	Methyltestosterone capsule 10mg	Remove from formulary. GF existing utilizers
Gout	Colchicine 0.6mg CAP	Add to formulary w/ QL of 9/month . Smart edit to bypass QL if member is receiving allopurinol.
DM (Sulfonylureas)	Chlorpropamide Tolazamide Tolbutamide	Remove from formulary. Very low utilization and other sulfonylureas are more cost-effective. GF existing utilizers
DM (TZD's)	Pioglitazone-Glimepiride Pioglitazone-Metformin	Remove from formulary. Individual products more cost-effective. GF existing utilizers
Antidepressants-MAOI's	Tranylcypromine Marplan	Remove from formulary. Very low utilization and other MAOI's are more cost-effective. GF existing utilizers
Antidepressants-TCA's	Desipramine Protriptyline	Remove from formulary. Multiple other TCA's available on formulary which are more cost-effective. GF existing utilizers
Statins	Rosuvastatin	Remove PA req'd and add ST through 60 days of atorvastatin

Formulary Changes – Calcitriol (SAI)

This SAI contains formulary recommendations based on clinical efficacy, safety and national treatment guideline recommendations. Formulary optimization across the Medicaid LOB can be achieved for all plans.

Background:

- Calcitriol, the active form of vitamin D3, is indicated for treatment of hypocalcemia in members on chronic renal dialysis, hypoparathyroidism, or secondary hyperparathyroidism with moderate to severe chronic kidney disease. Of the generic calcitriol products, there are 2 different formulations which include the oral solution 1mcg/1ml and oral capsules which come in two strengths: 0.25mcg/cap and 0.50mcg/cap.
- Currently calcitriol oral solution and oral capsules are covered on the standard formulary with no UM's.
- Current data suggests that there is no clinically meaningful difference in terms of efficacy and safety between the oral solution formulation and oral capsule formulation. The capsule formulation is liquid filled with gelatin capsule shells. Capsules contain fractionated triglyceride coconut oil while the solution contains fractionated triglyceride of palm seed oil. Both capsule and solution formulations can be used in compounding preparations that include calcitriol. The liquid from the capsule can be removed by puncturing the capsule with needle.

Recommendations:

- Recommend removing calcitriol oral solution from the formulary. (No GF)

Formulary Changes – Lidocaine Ointment (SAI)

This SAI contains formulary recommendations based on clinical efficacy, safety and national treatment guideline recommendations. Formulary optimization across the Medicaid LOB can be achieved for all plans.

Background:

- Lidocaine 5% ointment is indicated for Production of anesthesia of accessible mucous membranes of the oropharynx., Anesthetic lubricant for intubation, Temporary relief of pain associated with minor burns, including sunburn, abrasions of the skin, and insect bites.
- Currently, lidocaine 5% ointment is covered on the standard formulary with QLL (90g/30 days). Lidocaine 4% cream is covered on the standard formulary with no UM.
- Lidocaine 5% ointment utilization and cost/Rx have recently spiked .
- Lidocaine 5% ointment has been implicated in several FWA schemes involving pharmacies and prescribers.
- Current data suggests that there is no clinically meaningful difference in terms of efficacy and safety between lidocaine 5% ointment and lidocaine 4% cream. Lidocaine 4% cream has the same pain-relieving indications as lidocaine 5% ointment.
- Lidocaine Ointment 5% costs approximately $362/Rx where the 4% cream costs $31.08/Rx (Note: Lidocaine 4% Cream is an OTC product).
- Aetna commercial, Medicare, and MMP LOBs have implemented PA and QL requirements in 2018 for Lidocaine 5% ointment.

Recommendations:

- Recommend adding prior authorization requirements to lidocaine 5% ointment to steer new and existing lidocaine 5% ointment utilizers to lidocaine 4% cream.
- Prior authorization would require trial and failure of lidocaine 4% cream and a valid FDA-approved or compendia-supported diagnosis.

Formulary Changes – OTC Formulary

Refer to supporting document that lists the proposed OTC formulary coverage

Goal: Create a standard OTC formulary that includes products with sound clinical evidence and are cost-effective

Background and Development:

- Current formulary contains many products that have limited medical necessity for Medicaid population
- Current formulary also contains many products that are not on the CMS Rebate (labeler agreement) list
  - These products have a risk of rejected coverage encounters from the state
  - Products that did not provide value or create a potential gap in coverage were removed
- Current formulary is missing products that have sound clinical evidence of value to the Medicaid population

Coverage Guideline/Criteria Reviews

All coverage criteria and guideline reviews are presented in the attached file.

Annual review of guidelines considers national treatment recommendations/guidelines as applicable for topic at hand, factoring in formulary composition of like or related drug/drug classes. Guidelines were also reviewed with respect to impact to operational efficiencies relative to utilization control benefits provided.

Summary of the changes, plans the documents apply to and the full guideline document is provided for review.

Summary of Guideline Reviews

Guideline	Summary of Changes
Anthelmintics	The ICD 10 codes were replaced with the name of the infection
Antidepressants Non-Preferred	No updates

Atypical Antipsychotics	• Neurologists and developmental pediatricians were included as prescribers
	• Updated the monitoring wording to as follows:
	  • Baseline and yearly monitoring of blood glucose using a test for hemoglobin A1c (HBA1c) or blood glucose
	  • Baseline and yearly monitoring of cholesterol using a test of low-density lipoprotein-cholesterol (LDL-C) or cholesterol
	  • Monitoring weight at baseline and yearly
	  • Monitoring of movement disorders associated with antipsychotic therapy

Atypical Antipsychotics Long-Acting Injectable	• Added Abilify Maintena as a drug with an FDA approved indication for Bipolar I • Added dosing for Aristada 1,064 mg of 1 every 2 months
Buprenorphine	• Due to the recent governor's declaration of emergency around opioid use, updated verbiage for providers from one of the opioid use disorder center of excellence (OUD-COE) • Only requirement will be trial and failure with formulary agent buprenorphine/naloxone SL tablet

Summary of Guideline Reviews

Guideline	Summary of Changes

CNS Stimulants	• Removed the criteria for ages 6 through 18 years and replaced it with criteria for ages 6 -11 years and then 12-17 years:
	  • For Adolescents *Ages 12 through 17:*
	  • Member has a diagnosis of attention deficit hyperactivity disorder (ADHD/ADD) or narcolepsy
	  • In addition, members initiating stimulants for ADHD/ADD must meet the following:
	  • ADHD/ADD diagnosis is documented in the medical record and is based on a comprehensive evaluation by an appropriate specialist or primary care provider. The evaluation must include an evidence based rating scale (for example but not limited to Swanson, Nolan, Pelham-IV Questionaire (SNAP-IV).
	  • Other conditions (such as depression, anxiety, conduct disorder or tics) have been ruled out OR are being appropriately treated.
	  • For members with a history of substance abuse disorder, a urine drug screen is included in the treatment plan (urine drug screen does not need to be provided with request)

Summary of Guideline Reviews

Guideline	Summary of Changes
CNS Stimulants (continued)	• For Children Ages 6 through 11 includes the criteria for Ages 12 through 17 and the following: • Evidence-based behavioral therapy (child, teacher, and/or caregiver) has been considered as part of the treatment plan. The therapy can be ongoing, previously completed or noted as not appropriate or necessary in this case. • The requirement of failure of three formulary stimulants from both subclasses is being updated to two formulary stimulants from both subclasses • All ADHD products will require prior authorization
Corlanor	• Added NYHA Class II-III heart failure to the criteria per ACC/AHA 2017 guideline update • Modified renewal criteria to monitor HR response within 50-60 bpm or dose is adjusted accordingly to achieve target HR

Summary of Guideline Reviews

Guideline	Summary of Changes

Cytokines and CAM antagonists	• Added New FDA approved drugs and criteria:
	  • Kevzara(Sarilumab): RA
	  • Siliq (brodalumabitor): Moderate to Severe Plaque psoriasis
	  • Tremfya (guselkumab): Moderate to Severe Plaque psoriasis
	  • Added Biosimilar to Remicade: Renflexis, Inflectra
	• Actemra: Removed lab requirements for initial/renewal approval and added as note in dosing section
	• Removed requirement for genetic test for diagnosis of CAPS (Kineret, Ilaris)
	• Ilaris: added criteria for Familial Mediterranean fever (FMF)
	• Arcalyst: added to criteria for diagnosis of CAPS
	• Actemra (tocilizumab): Expanded indication of Giant cell arteritis (GCA) based on GiACTA trial
	• For AS/PsA: changed 3 month trial of NSAIDS to ≥ 1 month per American College of Rheumatology (ACR 2015) recommendations

Summary of Guideline Reviews

Guideline	Summary of Changes

Cytokines and CAM antagonists (continued)	• Plaque psoriasis:
	  • Enbrel: changed age 6 years to 4 year per PI
	  • Stelara: changed age 18 years to 12 per PI
	  • Added requirement for >10% of BSA
	  • Added mental health evaluation requirements for Siliq
	• Removed requirement for continued use of NSAID while on CAM antagonist for diagnosis of PSA/ ankylosing spondylitis and added as a note
	• HS: Added staging criteria per PI
	• Uveitis: Changed trial of corticosteroids and 2 steroid sparing immunosuppressive meds to trial of any of those agents based on 2014 Levy-Clarke et al expert panel recommendations.
	• Renewal criteria: Removed disease specific requirements and simplified verbiage
	• Updated quantity limit for Hidradenitis; added dosing for Kevzara, Actemra (GCA), Tremfya, Siliq; Inflectra, Renflexis
	• Added additional information for pharmacist: contraindications for MTX, NSAIDs

Summary of Guideline Reviews

Guideline	Summary of Changes
Diclegis	No updates
Direct Renin Inhibitors	• Tekamlo was discontinued and removed from the guideline • Criteria was added for children 6 years of age to include trial or inability to tolerate two drugs from the following classes: thiazide-type diuretic, calcium channel blockers, ACE Inhibitors and ARBs
Egrifta	• Updated to allow for diagnosis and risk for medical complications due to excess abdominal fat • Removed contraindication requirements • Initial approval was decreased from 1 year to 6 months and the renewal was decreased from 3 years to 1 year • Added examples of a positive response in the renewal section
Entresto	• Added requirement that member does not have a history of angioedema • Added requirement that member will not use Entresto within 36 hours of the last dose of an ACE inhibitor

Summary of Guideline Reviews

Guideline	Summary of Changes
Hyperlipidemia Medications	• Omtryg was discontinued and removed from the guideline • Removed the prior authorization criteria for rosuvastatin and replaced with step therapy of 60 day use of any strength of atorvastatin within the past 130 days
Intravaginal Progesterone Products	• Updated the criteria for cervical length to be less than or equal to 25 mm from less than 25 mm • Added criteria for secondary amenorrhea for Crinone requiring to be prescribed by or in consultation with a provider of obstetrical care and an inadequate response or intolerable side effects to, progesterone capsules • The following was added for secondary amenorrhea: the initial approval for the 4% gel is for a total of 6 doses, requests for the 8% gel will be approved for a total of 6 doses if the member did not respond to the 4% gel and requests for additional quantities will require a review.
Juxtapid/ Kynamro	• Removed requirements regarding failure/intolerance of statin therapy as these will be met in PCSK9 Inhibitor GL • Removed contraindications as listed at the end of the GL

Summary of Guideline Reviews

Guideline	Summary of Changes
Lysteda/ Tranexamic Acid Tablets	Added the language 'including retinal vein or artery occlusion' to the bullet history of thrombosis or thromboembolism
Makena	No updates
Multaq	• Added criteria for not having symptomatic heart failure with recent decompensation requiring hospitalization or NYHA Class IV heart failure • Removed miscellaneous Drug-Drug contraindication/precautions for the Class I and III anti-arrhythmics • Updated language that provider attests that no contraindications exists
Non-stimulant ADHD Medications	No update

Summary of Guideline Reviews

Guideline	Summary of Changes
Otezla	• Removed requirement that member is currently on an NSAID or has a contraindication • PSA: removed the ≥3 joints affected • Plaque Psoriasis: clarified as moderate to severe form of PsO; clarified requirement for > 10% of BSA or less for sensitive areas such as the hands, feet, etc • Removed symptoms are not controlled with topical therapy • Removed requirement that disease has significant impact on physical, psychological or social well being • Modified requirement for phototherapy to simply state PUVA or UVB has been ineffective • Removed response to therapy renewal requirement (20% improvement, experience of SI or depression and BMI level)
PCSK9 Inhibitors	Updated the requirements that define statin intolerance according to the American College of Cardiology
Xifaxan	No updates

New Guideline Reviews

Guideline	Guideline/Criteria Details
Emflaza	Emflaza is approved for members 5 years of age and older when ALL of the following criteria is met: • Prescribed by or in consultation with a neurologist • Diagnosis of Duchenne Muscular Dystrophy (DMD) confirmed by genetic testing demonstrating a mutation in the dystrophin gene OR abnormal dystrophin (prescriber must submit documentation) • Serum creatine kinase (CK) at least 10 times the upper limit of normal • Trial of prednisone for at least 6 months with unmanageable and clinically significant weight gain/obesity OR psychiatric/behavioral issues (such as abnormal behavior, aggression, irritability) (prescriber must submit documentation) • Emflaza will not be given concurrently with live vaccinations • Absence of active infection (including TB and Hepatitis B Virus). If member has a history of HBV infection, prescriber agrees to monitor for HBV reinfection.

New Guideline Reviews

Guideline	Guideline/Criteria Details
Emflaza (continue)	• Initial Approval: 6 months; Renewal: 12 months and Requires: Clinical benefit from Emflaza therapy (improvement or stabilization of muscle strength or pulmonary function), Not given concurrently with live vaccinations, and absence of active infection (including TB and Hepatitis B Virus). If member has a history of HBV infection, prescriber agrees to monitor for HBV reinfection.
Estrace/ Premarin Cream	Premarin cream and Estrace cream are approved when ONE of the following criteria is met: • Member had inadequate response, intolerable side effects, or contraindication to vaginal estradiol tablets (Vagifem) • OR • Member is 10 years of age or younger with a diagnosis of labial adhesion • Initial Approval: Premarin cream and Estrace cream for labial adhesions: 6 months

New Guideline Reviews

Guideline	Guideline/Criteria Details

Griseofulvin	Griseofulvin is approved when ONE of the following criteria is met:
	• Member had inadequate response, intolerable side effects, or contraindication to ONE
	  • fluconazole
	  • itraconazole
	  • ketoconazole
	  • terbinafine
	  OR
	• Member has a diagnosis of tinea capitis
	• Initial Approval: 6 months; Renewal: 6 months

New Guideline Reviews

Guideline	Guideline/Criteria Details

Lidocaine 5% Ointment	Lidocaine 5% Ointment is approved when **ONE** of the following criteria is met:
	• Diagnosis of ONE of the following:
	  • Production of anesthesia of accessible mucous membranes of the oropharynx OR
	  • Anesthetic lubricant for intubation
	• Member had inadequate response, intolerable side effects, or contraindication to lidocaine 4% cream and using for ONE of the following:
	  • For the temporary relief of pain associated with minor burns, including sunburn, abrasions of the skin, and insect bites OR
	  • For an FDA-approved or compendia-supported diagnosis for Lidocaine 5% Ointment
	• Initial Approval: 3 months

New Guideline Reviews

Guideline	Guideline/Criteria Details
Monoamine depletors (Ingrezza, Austedo, Tetrabenazine)	**Tardive Dyskinesia (Ingrezza, Austedo)** **Member must meet following criteria for initial approval:** • Member must be 18 years of age or older. • Member must have diagnosis of Moderate to severe tardive dyskinesia confirmed by neurologist consult. • Abnormal Involuntary Movement Scale (AIMS) score greater than or equal to 10. • Provider has attempted an alternative method to manage the condition (such as dose reduction, discontinuation of the offending medication or switching to alterative agents such as atypical antipsychotics). For Austedo: • Member does not have hepatic dysfunction • Member is not receiving concurrent therapy with monoamine oxidase inhibitor (MAOI) therapy (e.g., selegiline, reserpine) or additional VMAT2 inhibitor (e.g., tetrabenzaine, valbenazine) • Member is not actively suicidal or unstable psychiatric symptoms

New Guideline Reviews

Guideline	Guideline/Criteria Details
Monoamine depletors (Ingrezza, Austedo, Tetrabenazine) (continued)	For Ingrezza: • Member is not at risk for suicidal behavior or unstable psychiatric symptoms • Member does not have congenital long QT syndrome or with arrhythmias associated with a prolonged QT interval **Huntington's Chorea (Austedo, Tetrabenazine):** **Member must meet following criteria for initial approval:** • Member must be 18 years of age or older. • Diagnosis confirmed by neurologist consult and genetic testing • Total Maximal Chorea Score of 12 or greater • Member has tried, or is unable to use amantadine • Member does not have hepatic dysfunction • Member is not receiving concurrent therapy with monoamine oxidase inhibitor (MAOI) therapy (e.g., selegiline, reserpine) or additional VMAT2 inhibitor (e.g., tetrabenzaine, valbenazine) • Member is not actively suicidal or unstable psychiatric symptoms

New Guideline Reviews

Guideline	Guideline/Criteria Details
Monoamine depletors (Ingrezza, Austedo, Tetrabenazine) (continued)	**Initial Approval:** **Tardive Dyskinesia** 2 months **Huntington's Chorea** 3 months Note: Initial approval must be done by Medical director (Rph must send to MDR for final decision) **Renewals:** 1 year **Tardive Dyskinesia** Documented improvement in AIM score (decrease from baseline by at least 2 points). **Huntington's Chorea** Documented improvement from baseline in Total Maximal Chorea score (3 points or greater)

New Drug Coverage Provisions

New Drugs to the market default to Non-formulary status and our standard non-formulary process until they can under go their formal P&T review.

The standard non-formulary process is to review for the following criteria: The drug is being used for it's FDA approved indication.

The member has tried and failed at least two formulary alternatives that treat the same condition.

Specialty/High Cost medications also require MDR review for all requests regardless of the decision.

The Subcommittee will work to create interim guidelines for the clinical pharmacists and Medical Directors use until formal criteria can be developed and approved by the P&T either at a quarterly meeting or by ad hoc e-vote.

Abbreviated New Drug Reviews

Drug	Class	Indication	Efficacy	Proposal	Comments
Benznidazole 12.5 mg, 100mg Tab	Antiprotozoal	Treatment of Chagas disease caused by *Trypanosoma cruzi* in pediatric patients two years of age to 12 years of age.	Approval for benznidazole was based on two randomized, double-blind, placebo-controlled, phase III clinical field trials that evaluated the efficacy and safety of benznidazole in pediatric patients with chronic indeterminate Chas disease Patients receiving benznidazole had a higher rate of conversion to a negative serological status compared with patients receiving placebo by the end of the follow up period.	Non-Preferred	First treatment FDA approved for indication Both the 2017 CDC guidelines and the 2017 WHO guidelines for Chagas disease recommend either benznidazole or nifurtimox (Brazil) for the treatment of patients with Chagas disease.
Calquence® (acalabrutinib 100 mg) Cap	Antineoplastic Agent, Tyrosine Kinase Inhibitor	Treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.	Approval for Calquence was based on preliminary data from an ongoing, open-label, multicenter, single-arm, phase II clinical trial that evaluated the efficacy and safety of Calquence in patients with relapsed or refractory MCL Patients receiving Calquence had an overall response rate (primary endpoint) of 81%, with a complete response rate of 40% and a partial response rate of 41% Estimated completion date for clinical trial is September 2019	Non-Preferred	Calquence is the second FDA approved BTK inhibitor The 2017 NCCN Clinical Practice Guidelines in Oncology for MCL recommend Calquence, Imbruvica, chemotherapy regimens ± Rituxan, Velcade ± Rituxan, Revlimid± Rituxan, Venclexta, radiation therapy, or enrollment in a clinical trial for patients requiring second line therapy.

Abbreviated New Drug Reviews

Drug	Class	Indication	Efficacy	Proposal	Comments
Fasenra™ (benralizumab 30 mg/mL) **SC Inj**	Antiasthma, Interlukin-5 receptor alpha-directed cytolytic monoclonal antibody (IgG1, kappa)	Add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.	The efficacy of Fasenra in the treatment of severe asthma in patients with blood eosinophil ≥300 cells per μL was evaluated in two phase III trials that compared Fasenra to placebo. Results demonstrated that Fasenra achieved a statistically significant reduction in asthma exacerbation rates and improvement in lung function (FEV_1). Fasenra, an as an oral corticosteroid-sparing therapy was evaluated in one phase III trial demonstrating statistically significant reductions in oral corticosteroid use compared to placebo.	Non-Preferred	Fasenra is the third FDA approved drug after Nucala and Cinqair for this indication Fasenra has a novel MOA which targets IL-5Rα, inducing antibody-dependent cell-mediated cytotoxicity. In contrast to Nucala and Cinqair, Fasrena induces direct depletion of eosinophils and may avoid the potential issue of cytokine-directed antiobodies.
Mepsevii™ (vestronidase alfa-vjbk 10 mg/5mL) **Inj**	Endocrine-Metabolic Agent, Enzyme	Treatment of mucopolysaccharidosis VII (MPS VII), also known as Sly syndrome, in pediatric and adult patients	The efficacy of Mepsevii was based on a phase III, multinational, placebo-controlled, blind-start randomized, single crossover trial in 12 patients 5 years of age to 35 years of age with MPS VII. Treatment with Mepsevii 4mg/kg IV every other week resulted in a significant decrease in the urinary GAGs dermatan sulfate (-64.8%; p <0.0001) and chondroitin sulfate (-70.6%; p< 0.0001) at 24 weeks. Treatment with Mepsevii also improved some aspects of clinical response, including fatigue and FVC.	Non-Preferred	Mepsevii is the first ERT option for this indication. Hematopoietic stem cell transplantation is the only other treatment available for MPS VII, but its use is limited by few appropriate donors as well as high mortality and morbidity rates. There are no treatment guidelines for MPS VII.

Abbreviated New Drug Reviews

Drug	Class	Indication	Efficacy	Proposal	Comments
Parsabiv™ (etelcalcetide 2.5mg/0.5mL , 5mg/mL, 10mg/2mL) **Inj**	Calcimimetic, Endocrine-Metabolic Agent	Secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on hemodialysis	The safety and efficacy of Parsabiv were evaluated in two randomized, controlled trials comparing Parsabiv to placebo and one trial comparing Parsabiv with oral Sensipar. Over 26 weeks, in patients receiving HD with moderate-to-severe secondary HPT, Parsabiv resulted in a greater proportion of patients achieving > 30% reduction in serum PTH compared with placebo. Over 26 weeks, in patients receiving HD with moderate-to-severe secondary HPT, Parsabiv was noninferior to Sensipar in proportion of patients achieving > 30% reduction from baseline in mean PTH and also met superiority criteria.	Non-Preferred	The KDIGO guidelines recommend calcitriol, vitamin D analogs, calcimimetics, or a combination to be used to lower PTH in patients with stage 5 CKD receiving HD with elevated or rising PTH. Parsabiv is administered by iV injection three times a week post-HD, while Sensipar, the only other FDA-approved calcimimetic is administered orally once daily.
Solosec™ (secnidazole 2gm) **oral granules**	Antibiotic, Anti-Infective agent	Treatment of bacterial vaginosis in adult women	The efficacy of Solosec was established in two multicenter, double-blind, randomized, placebo-controlled pivotal trials in non-pregnant women with a diagnosis of BV: • In the phase II trial (N=124), a single 2g dose of Solosec was superior to placebo in terms of clinical cure rate (67.7% vs. 17.7%; p< 0.001) and microbiologic cure rate (40.3% vs. 6.5%; p<0.001) • In the phase III trial (N= 164), a single 2-g dose of Solosec was superior to placebo in terms of clinical cure rate (53.3% vs. 19.3%; p<0.0001) and microbiologic cure rate (43.9% vs. 5.3%, respectively; p< 0.001)	Non-preferred	The CDC in 2015 recommended oral metronidazole, intravaginal metronidazole gel, and intravaginal clindamycin cream for treating BV. Solosec is one of two orally available antimicrobial agents for this indication Compared with tinidazole, Solosec is administered as a single dose without regard to food or alcohol.